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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,316	08/20/2001	Stephen C Porter	8600-0029	7064
20855 7590 02/08/2007 ROBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94303			EXAMINER CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
2 MONTHS		02/08/2007	PAPER	

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

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Application Number: 09/933,316
Filing Date: August 20, 2001
Appellant(s): PORTER, STEPHEN C

FEB 08 2007

TECH CENTER 1600/2900

Dahna S. Pasternak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/22/2006 appealing from the Office action mailed 3/27/2006.

(1) *Real Party in Interest*

A statement identifying by name the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) *Summary of Claimed Subject Matter*

The summary of the claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) *Claims Appendix*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) *Evidence Relied Upon*

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Krall et al. (WO 00/44287)

Ricci et al. (US Patent 6,203,779)

Hechenberger et al. (US Patent 4,997,861)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,3-4, 9-11, 15-28, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al. WO 00/44287 (WO '287) in view of Ricci et al. US patent 6,203,779.

Krall discloses compositions comprising the two components of M1 and M2 (abstract; example 6, pages 50-53). M1 meets the limitation of the instant matrix-

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forming material because it contains 2-Hexyl Cyanoacrylate, which is an alkyl cyanoacrylate monomer in amounts of about 49% wt in total formulation. (see page 18, lines 18-20, example 4, page 47). M1 further contains hydroquinone, p-methoxyphenol and phosphoric acid as the stabilizers (page 6, lines 24-33; page 7, lines 1-26; page 19, lines 20-25, page 62, claims 1-9). Krall uses and claims such amounts of hydroquinone and phosphoric acid that falls within the ranges of the instant claim 20 (see page 63, lines 11-20). Krall also discloses the use of n-butyl cyanacrylates in amounts of about 33% wt. (see examples 4-5, 7, pages 47-54).

The M2 component of Krall contains a radiopaque moiety, which can be pure gold powder, iodinated oil or other like agents (page 17, lines 1-10; page 26, lines 18-26; page 27, lines 1-25). Krall specifically uses powdered gold, which meets the instant solid aggregate material limitation of claim 1 (page 50, line 15; example 6).

The ethyl myristate and the Ethiodol of Krall also anticipate the plasticizer component of instant claim 1 and 26, because they are respectively an alkyl ester and an iodinated oil and fall within the plasticizers enumerated in the instant claims 25-26. (see page 64, lines 1-6; and page 65, lines 15-18).

Krall's composition only lacks a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000.

Ricci describes embolic compositions comprising a polymer which falls within the scope of the instantly claimed non-cyanoacrylate rheology modifying agents. Ricci specifically describes the use of polymers or prepolymers that can either be cyanoacrylates or non-cyanoacrylates biocompatible polymers. The non-cyanoacrylate

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polymers described by Ricci include cellulose acetate, polymethylacrylates, or ethylene vinyl alcohol copolymers. (see col 5, lines 1-40; col 6, lines 56-67; col 9, lines 15-24).

The cellulosic polymers of Ricci have an average molecular weight of about 200,000. (see col 5, lines 33-35). Ricci explicitly states that adjustment of the viscosity of the composition can be readily achieved by mere adjustment of the molecular weight of the polymer in the compositions. (see col 5, lines 39-41). Therefore, for purposes of adjusting the viscosity of an embolic compositions, all biocompatible polymers described by Ricci are functional equivalents.

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a non-cyanoacrylate biocompatible polymer of Ricci including its methylacrylates or cellulosic polymers to the embolic composition of Krall and optimize the viscosity of such compositions for their own intended purpose by routine experimentation, because both polymeric units of Krall and Ricci are equally effective as embolic compositions.

Claims 1, 3-4, 9-11, 15-28, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al. in view of Ricci as applied to claims 1, 3-4, 9-11, 15-28, 39-41 and further in view of Hechenberger et al. US Patent 4,997,861.

The teachings of Krall and Ricci are described above. Their combined teachings do not use an inorganic particulate material such as fumed silica.

Hechenberger teaches polymeric adhesive compositions containing cyanoacrylate and non-cyanoacrylate polymers in combination with fumed silica (abstract; col 4). Hechenberger suggests that use of non-cyanoacrylate polymers and an inorganic thickener such as fumed silica provides improves stability and adhesive properties of cyanoacrylate polymeric adhesive agents (see col 2, lines 63-col 3, lines 20).

Accordingly since Hechenberger suggests that addition of fumed silica would improve adhesive properties of cyanoacrylate compositions, it would have been obvious to one of ordinary skill in the art at the time of invention to further add fumed silica to the formulations of Krall and Ricci, because the ordinary skill in the art would have had a reasonable expectation of success to enhance the adhesive properties of such compositions.

(10) *Response to Argument*

Appellant argues that Ricci does not teach rheology modifying agents having molecular weights greater than 200,000.

The rejection states that the cellulosic polymers of Ricci have an average molecular weight of about 200,000. (see Ricci at col 5, lines 1-40; col 6, lines 56-67; col 9, lines 15-24; specially col 5, lines 33-35). Examiner views the language "about 200,000" in Ricci, to also include slightly greater than 200,000. Accordingly, the rejection has already taught all features of the instant claims.

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Moreover, the rejection concluded that it would have been obvious to one of ordinary skill in the art at the time of invention to combine non-cyanoacrylate biocompatible polymer of Ricci and the embolic composition of Krall and further optimize the viscosity of such compositions for their own intended use by routine experimentation. Therefore, even if Ricci does not explicitly meet such limitation, the rejection has articulated that the instantly employed molecular weight was viewed as an optimizable parameter.

Examiner adds that Ricci teaches the same polymers as instantly employed. Since all such homologous polymers moieties will provide viscosity or rheology characteristics, modifying their molecular weights would have amount to a mere difference in degree. The Courts have repeatedly reasoned that mere difference in effectiveness is regarded as a mere difference in degree and not render patentable compounds rejected on structural obviousness. *Deutsche Gold-und-Sibler, etc., v. Comr. Pats*, 148 USPQ323. (DCDC 1966). Here, the difference argued by Appellant is merely a difference in degree of molecular weights of the cellulosic polymers disclosed by Ricci, because it would optimize the rheological characteristics of an embolic composition. However, absent a showing of unexpected results modifying viscosity of such compositions by recognizing the preferred molecular weight of the ingredients would have been achieved by routine experimentation.

Appellant argues that Ricci does not disclose a composition that includes a solid cyanoacrylate.

This is not persuasive because the Ricci reference was used to combine non-cyanoacrylate polymers with the solid composition comprising cyanoacrylate polymers disclosed by Krall. Accordingly, Krall already teaches that the cyanoacrylate polymer containing compositions are already solids. Furthermore, there is no limitation found in the claims regarding where the cyanoacrylate polymers must be solid.

In response to Appellant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Appellant argues that that Ricci teaches the use of "biocompatible prepolymers" and they are not combinable with cellulose diacetate polymers, which are "biocompatible polymers." Appellant argues that they are not interchangeable and that they are meant to be used separately or in the alternative.

In response Examiner states that there is absolutely no teaching in Ricci discouraging the combination of the biocompatible polymers with the biocompatible prepolymers, both of which can be used for the same intended use. In the instant case, combining two polymeric moieties that are used for the same purpose, namely for embolic compositions, is knowledge generally available to one of ordinary skill in the art.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their

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having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In response to Appellant's argument that there is no suggestion to combine the references, Examiner states that Appellant fails to evaluate the references by what they suggest to one versed in the art rather than by their specific disclosure. Furthermore, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, combining two polymeric moieties that are used for the same purpose is knowledge generally available to one of ordinary skill in the art.

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding the establishment of unexpected results or synergism, a few notable principles are well settled. The Appellant has the initial burden to explain any proffered

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data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). It is Appellant's burden to present clear and convincing factual evidence of nonobviousness or unexpected results, i.e., side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art. The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). With regard to synergism, a prima facie case of synergism has not been established if the data or result is not obvious. The synergism should be sufficient to overcome the obviousness, but must also be commensurate with the scope of the claims. Further, if the Appellant provides a DECLARATION UNDER 37 CFR 1.132, it must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See MPEP 716.02 (e).


In the instant case, Examiner does not view the disclosed new properties as unexpected but rather expected results.

(11) *Related Proceeding(s) Appendix*

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

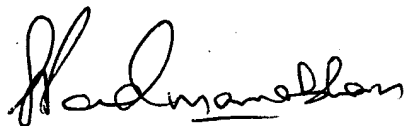

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January 30, 2007

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